

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellants:	Charles G. Hwang et al.	Examiner:	Witczak, Catherine
Application No.:	10/691,385	Group Art Unit:	3767
Confirmation No.:	8673	Docket No.:	102-539 CIP/RCE III (P-6048/1)
Filing Date:	October 22, 2003	Dated:	July 15, 2009
Title:	SYRINGE TIP CAP		

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF

Sir:

Appellants have appealed the Final Rejection of Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 dated January 15, 2009. This Brief is submitted in accordance with the provisions of 37 C.F.R. §41.37. As required by 37 C.F.R. §41.20(b)(2), please charge Deposit Account No. 08-2461 the requisite fee of \$540.00 for submitting a Brief in support of an appeal. If additional fees are required, please charge Deposit Account No. 08-2461.

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I. Real Party In Interest

The subject application is owned by Becton, Dickinson and Company.

II. Related Appeals and Interferences

There are no known related appeals or interferences.

III. Status of Claims

Claims 1-34, 37, and 38 are pending.

Claims 3-7, 10, 13, 17-21, 25-27, 29, and 30 have been withdrawn.

Claims 35 and 36 have been cancelled.

Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 are finally rejected and on appeal.

No claims presently stand allowed.

IV. Status of Amendments

In a Final Office Action of January 15, 2009, the Examiner finally rejected Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 of the above-identified application. No amendments have been filed subsequent to the final rejection.

V. Summary of Claimed Subject Matter

The subject invention relates to a tip cap 10 for a syringe 200 for a medicament. (p. 1, ll. 11-12). The tip cap 10 includes a cap body 12 having a top wall 14 and a depending sealing base 16, and further includes a shaft 18 for connecting to and disconnecting from a syringe 200. (p. 7, ll. 14-16; Fig. 1). The shaft 18 and the cap body 12 form a single unitary tip cap 10 for receiving a force imparted to the top wall 14 which causes the tip cap 10 to rotate and connect to or disconnect from a syringe body. (p. 7, ll. 16-18).

The top wall 14 is a non-circular tubular structure, extending upwardly from the sealing base 16. (p. 7, ll. 18-19; Figs. 1, 4). The sealing base 16 is a substantially flat surface having top 16a and bottom 16b faces respectively. (p. 7, ll. 19-20). The top wall 14 is joined to sealing base top 16a, preferably about at least the majority of its perimeter, and the shaft 18 is joined to sealing base bottom 16b. (p. 7, ll. 20-22). The non-circular top wall 14 provides an elongated gripping surface 50. (p. 9, ll. 3-5; Figs. 2-4).

There are two independent claims on appeal, Claim 1 and Claim 15. Claims 1 and 15 are set forth below with reference numbers and citations to the specification and drawings:

1. A tip cap 10 for a syringe 200 for a medicament, the syringe 200 having a tip 220, said tip cap 10 comprising a base portion 16 having an upper surface 16a and a lower surface 16b, a body 12 having a top wall 14 extending from said upper surface 16a and self-maintained in having a substantially non-circular cross-section in an unstressed condition when viewed at an angle substantially perpendicular to said upper surface 16a, and a shaft 18

extending from said lower surface 16b, said shaft 18 being shaped internally to releasably receive the tip 220 of the syringe 200, wherein said tip cap 10 defines a continuous and uninterrupted sealing surface which continuously seals the tip 220 of the syringe 200 and contains the medicament within the syringe 200 when said tip 220 is releasably received in said shaft 18 of said tip cap 10 and until said tip cap 10 is removed from said syringe 200, the medicament within the syringe 200 being accessible through the tip 220 of the syringe 200 with removal of said tip cap 10 (p. 7, ll. 14-22; p. 8, ll. 2-5; p. 9, ll. 1-5; Figs. 1-4).

15. A syringe assembly comprising:

a syringe 200 having a tip 220 (P. 8, ll. 4-5; Fig. 2); and

a tip cap 10 securable to said tip 220 (P. 8, ll. 7-12; Fig. 2) and comprising:

a base portion 16 having an upper surface 16a and a lower surface 16b, a body 12 having a top wall 14 extending from said upper surface 16a and self-maintained in having a substantially non-circular cross-section in an unstressed condition when viewed at an angle substantially perpendicular to upper surface 16a, and a shaft 18 extending from said lower surface 16b, said shaft 18 being shaped internally to releasably receive the tip 220 of the syringe 200, wherein said tip cap 10 defines a continuous and uninterrupted sealing surface which continuously seals the tip 220 of the syringe 200 and contains the medicament within the syringe 200 when said tip 220 is releasably received in said shaft 18 of said tip cap 10 and until said tip cap 10 is removed from said syringe 200, the medicament within the syringe 200 being accessible through the tip 220 of the syringe 200 with removal of said tip cap 10 (p. 7, ll. 14-22; p. 8, ll. 2-5; p. 9, ll. 1-5; Figs. 1-4).

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VI. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:

1. Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 have been rejected under 35 U.S.C. §102(b) as being anticipated by Adams (U.S. Patent No. 2,585,527) ("Adams").

2. Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wallace et al. (U.S. Design Patent No. D457,954) ("Wallace") in view of Rowekamp (U.S. Patent No. 4,535,906) ("Rowekamp").

VII. Argument

A. Rejection of Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31, 32, 37, and 38 under 35 U.S.C. §102(b)

1. Legal Background

The first step in the analysis of anticipation is claim construction. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1346 (Fed. Cir. 2000), *see also*, *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 714, 48 U.S.P.Q.2d 1911, 1915 (Fed. Cir. 1998). Although claim terminology is to be given its broadest reasonable interpretation during examination, that interpretation must be consistent with the specification and with the interpretation that those skilled in the art would reach. *See* MPEP § 2111. As set forth at MPEP § 2111,

The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon

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giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." . . . Indeed, the rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms may be ascertainable by reference to the description."
37 CFR 1.75(d)(1).

MPEP § 2111 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005)).

The second step in an anticipation analysis "involves a comparison of the construed claim to the prior art." *Helifix Ltd.*, 208 F.3d at 1346. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987), *see also In re Gleave*, 90 U.S.P.Q.2d 1235, 1237-38 (Fed. Cir. 2009), *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1375, 81 U.S.P.Q.2d 1324, 1328 (Fed. Cir. 2006). Moreover, "each and every limitation of the claimed invention[,] . . . must be enabling[,] and [must] describe...[the] claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." *In re Paulsen*, 30 F.3d 1475, 1478-79, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

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2. Adams Does Not Anticipate Appellants' Claimed Invention

Adams does not disclose each and every limitation of the claims on appeal and, thus, does not anticipate the appealed claims.

a. Adams does not disclose a closure for syringes

Adams is directed to a slitted resilient closure for containers. (Title of Adams). The closure of Adams is "for containers from which pastes, liquids, powders, and like materials are dispensed." (Col. 1, ll. 1-3 of Adams). Adams is not for use with syringes, nor does Adams disclose a syringe, even under a broad interpretation of that term.

Claims 1 and 15 are the only independent claims on appeal. Claims 1 and 15 are directed to a tip cap and a syringe assembly, respectively. In particular, claim 1 is directed to a tip cap "for a syringe for a medicament" with the tip cap affirmatively including a shaft, "said shaft being shaped internally to releasably receive the tip of the syringe." Claim 15 is directed to a syringe assembly which includes "a syringe having a tip" and "a tip cap securable to said tip".

Appellants have previously argued that Adams does not disclose a syringe. In response to Appellants' previous arguments, the Examiner has stated,

Applicant argues that Adams does not disclose a syringe. Examiner disagrees. The broadest definition of syringe as provided by Merriam Webster Online dictionary is "a device used to inject fluids into or withdraw them from something," which defines the device of Adams.

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(pp. 2-3, Final Office Action of May 22, 2008).

However, the Examiner's position is incorrect. Claims are to be given the broadest interpretation *consistent with the specification and with the interpretation of those skilled in the art*. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 U.S.P.Q.2d 1321 (Fed. Cir. 2005). The Examiner is applying a definition of a syringe without any reference to the subject specification. Per the Examiner, any device which injects or withdraws fluid is a syringe.

Paragraphs [0003] – [0005] of the subject application clearly describe medical syringes for injection. Paragraphs [0006] – [0010] of the subject application clearly discuss prior art tip caps for use with medical syringes for injection. Paragraphs [0029] – [0030] of the subject application clearly discuss the use of the tip cap of the subject invention with syringes. (See also Figure 2 of Appellant's application). The syringes discussed in Appellants' specification are clearly medical syringes for injection. The term syringe in claims 1 and 15 must be interpreted in view of the specification and as how one skilled in the art would construe this term. It is clear that the term syringe in the claims on appeal is directed to a syringe for medical injections.

In contrast, Adams clearly states that the closure is for a container, such as a collapsible tube for pastes, liquids, and powders. Nowhere in Adams does Adams refer to a contrary usage, or reference a medical syringe for injections. The Adams device is not intended for injecting into or withdrawing from something as set forth in the Examiner's

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definition -- Adams does not even meet the definition proposed by the Examiner for a syringe (i.e., "a device used to inject fluids into or withdraw them from something"). No syringe is disclosed in Adams. Accordingly, Adams does not disclose each feature of claims 1 and 15.

b. Even if Adams would be applicable to a syringe, each and every element of the claimed invention is not disclosed in Adams

Adams is directed to a slitted resilient closure for containers. (Title of Adams). Adams requires the closure to include a slit, which can be opened or closed, to allow for dispensing material. (Col. 2, ll. 6-9 of Adams). The closure includes a cap 13 formed of a resilient, distortable material with an incision present that defines the slit. (Col. 2, ll. 32-35 of Adams). As such, Adams requires an openable incision which provides access to the contents of the container and permits dispensing therefrom when the closure is in the opened position. Clearly, the closure of Adams cannot be modified to avoid the incision, as such modification would render the device of Adams inoperable.

In the present case, the Examiner relied on Adams, which includes a closure with a slit that may be opened and closed. The closure allows dispensing of contents when the closure is open. The Examiner's reliance on Adams is misplaced. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros.*, 814 F.2d 628 at 631, 2 U.S.P.Q.2d at 1053. "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson*, 868 at 1236, 9 U.S.P.Q.2d at 1920.

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In Appellants' claimed invention, the shaft of the tip cap is shaped to releasably receive the tip of the syringe. The shaft configuration is arranged such that the tip of the syringe is sealed by the shaft in a continuous and uninterrupted manner when the tip cap is attached to the syringe. In particular, both claims 1 and 15 state: "said tip cap defines a continuous and uninterrupted sealing surface which continuously seals the tip of the syringe and contains the medicament within the syringe when said tip is releasably received in said shaft of said tip cap and until said tip cap is removed from said syringe". With this configuration, medicament is only accessible through the tip of the syringe by removal of the tip cap. In addition, the tip cap claimed by Appellants maintains the sterility of the tip of the syringe.

Adams does not provide a continuous and uninterrupted sealing surface; rather, Adams provides an incised, discontinuous and interrupted surface. In contrast, Appellants' claimed invention provides a continuous and uninterrupted seal of the tip of the syringe. Appellants' claimed invention requires removal of the tip cap prior to allowing access to the medicament contained in the syringe. Thus, the elements of Adams are not arranged or combined in the same manner since Adams has an interrupted and discontinuous sealing surface. In fact, the device disclosed by Adams is intended to enable a user to selectively dispense the contents of the container while the cap is in place. That is in contrast to Appellants' claimed invention, which seals the tip of a syringe and prevents medication from being dispensed until the cap is removed from the tip of the syringe. For Appellants' invention, the content of the syringe cannot be dispensed while the inventive tip cap is in place on the tip of the syringe. The

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contents of the syringe upon which Appellants' cap is secured can only be dispensed upon removal of the cap.

Furthermore, Adams can not be modified to anticipate Appellants' claimed invention because the incision is absolutely required in Adams to permit dispensing from the associated container. Clearly, Adams' closure with an incision does not anticipate Appellants' tip cap for sealing a syringe.

B. Rejection of Claims 33 and 34 Under 35 U.S.C. §102(b)

Claims 33 and 34 depend from claims 1 and 15, respectively. Both claims include the limitation of "wherein the syringe is a medical syringe."

As discussed above, the term "syringe" of the claims must be construed in view of the subject specification. As indicated above, it is respectfully submitted that the term "syringe" should be construed as covering medical syringes for injection. The limitation of claims 33 and 34 of "medical syringe" further highlights this interpretation.

C. Rejection of Claims 1, 2, 8, 9, 11; 12, 14-16, 22-24, 28, 31-34, 37, and 38 Under 35 U.S.C. §103(a)

1. Summary of Rejection

In the Final Office Action of January 15, 2009, the Examiner rejected Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 under 35 U.S.C. §103(a) as being unpatentable

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over Wallace in view of Rowekamp. The Examiner admitted that Wallace does not disclose "the body having a non-circular cross-section." (p. 3, Final Office Action of January 15, 2009). To overcome the deficiency, the Examiner asserted that Rowekamp discloses "a cap having a body with a non-circular cross section." (p. 3, Final Office Action of January 15, 2009). The Examiner concluded,

[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wallace et al with an elliptically shaped body as taught by Rowekamp, since such a modification would provide the device with an easier gripping shape providing better torque when opening/closing the cap.

(p. 3, Final Office Action of January 15, 2009).

2. Legal Background

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385, 1391 (2007) ("KSR") reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), but stated that the Federal Circuit erred by applying the teaching-suggestion-motivation test (TSM). The Court in *KSR* emphasized "the need for caution in granting a patent based on the combination of elements found in the prior art." *Id.* at 1395. The Court in *KSR* reiterated the framework for determining obviousness based on the following factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966):

- (A) Determining the scope and content of prior art;
- (B) Ascertaining the differences between the claimed invention and the prior art; and
- (C) Resolving the level of ordinary skill in the pertinent art.

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"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). "[O]bviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). As set forth at MPEP § 2143.01(III), "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." See *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 420, 127 S.Ct. 1727 (2007).

3. The Examiner has Failed to Make a *Prima Facie* Showing of Obviousness.

a. The rejection does not produce the claimed invention

Claims 1 and 15 are the only independent claims on appeal. Claims 1 and 15 are directed to a tip cap and a syringe assembly, respectively. As set forth in claims 1 and 15, the tip cap has "a base portion with an upper surface and a lower surface" and "a body having a top wall extending from said upper surface and self-maintained in having a substantially non-circular cross-section in an unstressed condition when viewed at an angle substantially perpendicular to the upper surface". As set forth in claims 1 and 15, the tip cap further has "a shaft extending from said lower surface, being shaped internally to relaseably receive the tip of the syringe".

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Wallace is a design patent which shows a syringe tip cap having a base portion with an upper surface and a lower surface. The upper surface, as admitted by the Examiner, is circular in shape. The Examiner expressly admitted that Wallace fails to disclose "the body having a non-circular cross-section." (p. 3, Final Office Action of January 15, 2009). The Examiner relied on Rowekamp for the disclosure of "a cap having a body with a non-circular cross-section." (p. 3, Final Office Action of January 15, 2009).

Rowekamp is directed to a bottle having an overcap 30 for attaching to container 10. The overcap 30 includes a top planar portion 34 and a skirt member 36 extending downwardly along the periphery of the top planar portion 34. (Col. 3, ll. 51-55 of Rowekamp). A side wall 37 also extends downwardly from the top planar portion 34. (Col. 3, ll. 51-55). The side wall 37 is located interiorly of the skirt member 36 and is formed with threads 38, 38' for mounting onto threads 26, 26' of neck 22 of the container. (Col. 3, l. 41 – col. 4, l. 15; Fig. 4).

In formulating the rejection on appeal, the Examiner asserted:

Wallace et al disclose the claimed invention except for the body having a non-circular cross-section. Rowekamp discloses in Figure 1 a cap having a body with a non-circular cross-section. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wallace et al with an elliptically shaped body as taught by Rowekamp, since such a modification would provide the device with an easier gripping shape providing better torque when opening/closing the cap.

(p. 3, Non-final Office Action of August 26, 2008).

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Accordingly, the Examiner modified the cap of Wallace to include an elliptically shaped skirt extending from the upper surface of the cap. However, the modification to Wallace suggested by the Examiner is not consistent with the cap design disclosed in Wallace and the overcap disclosed in Rowekamp. The Examiner's reliance on the combination of Wallace and Rowekamp is misplaced.

Rowekamp does not disclose having a top wall which extends from the upper surface of a base portion. Rather, the top portion 34 of Rowekamp is planar and the skirt 36 and the side wall 37 depend downwardly from the top portion 34. With any hypothetical combination of Wallace and Rowekamp, the lower, not upper, surface of Wallace would be modified to have the shape of the skirt 36 disclosed in Rowekamp. There is no disclosure or suggestion in either of Wallace or Rowekamp to use a non-circular top wall as set forth in Claims 1 and 15.

"In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). "[O]bviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)).

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In the present case, the Examiner erroneously asserted that Rowekamp has an elliptically shaped top wall extending from an upper surface. In response to Appellants' previous arguments, the Examiner stated:

Applicant argues that with any hypothetical combination of Rowekamp and Wallace et al. the lower, not upper portion of Wallace et al. would be modified by [sic] have the shape of the skirt (36) [sic] disclosed by Rowekamp. Examiner disagrees. The Rowekamp reference teach a cap having a [sic] two sections: a section (37) which is used to attach the cap to the container, and a noncircular portion (36) which is gripped by the user when attaching the cap to the container. Wallace et al. disclose a device also comprising two sections: a lower portion used to attach the cap to the syringe and an upper portion which the user would grasp when attaching the tip to the syringe. Thus, it is the Examiner's position that it would be obvious that when combining the teaching of Rowekamp to the device of Wallace et al., it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the *upper* portion (not the lower portion as argued by Applicant) of Wallace et al. **with the *upper noncircular portion of Rowekamp*** in order to provide the cap with an easier gripping shape which provide better torque when opening/closing the cap.

(p. 3, Final Office Action of January 15, 2009). (Bold added).

Thus, the Examiner considers the skirt member 36 in Rowekamp to be an "upper portion."

This, however, is inconsistent with the claims.

With reference to Claims 1 and 15, Claims 1 and 15 indicate that the tip cap includes "a base portion having an upper surface and a lower surface." Further, Claims 1 and 15 state that "a top wall extending from said upper surface" and "a shaft extending from said lower surface." Thus, the top wall and the shaft extend in opposite directions from the base portion.

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In addition, the top wall is provided with "a substantially non-circular cross-section". Further, "said shaft being shaped internally to releasably receive the tip of the syringe."

In the corresponding structure, Rowekamp includes a base portion having an upper surface and a lower surface with no structure extending upwardly from the upper surface. Rather, both the circular portion (side wall 37) for threading onto a neck of a container and the skirt member 36 extend both from the lower surface of the base portion. Contrary to the Examiner's assertion in the Office Action, there is no "*upper* noncircular portion of Rowekamp."

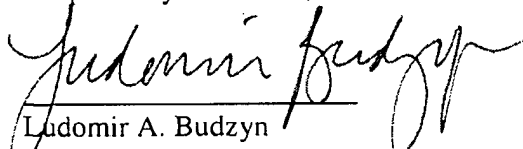
Thus, Rowekamp does not support the Examiner's suggested modifications to Wallace to include a non-circular upper wall. If anything, Rowekamp modifies the lower, syringe tip receiving shaft of Wallace. As illustrated above, the combination of Wallace and Rowekamp fails to support an obviousness rejection. As set forth at MPEP § 2143.01(III), "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the results would have been predictable to one of ordinary skill in the art." *See KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 420, 127 S.Ct. 1727 (2007). The mere possibility of combining Wallace and Rowekamp does not result in a finding of obviousness. The resultant combination of Wallace and Rowekamp is not obvious because all elements of Appellants' Claims 1 and 15 are not found in the prior art.

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C. Conclusion

Adams does not anticipate Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38. Moreover, Claims 1 and 15, along with dependent Claims 2, 8, 9, 11, 12, 14, 16, 22-24, 28, 31-34, 37, and 38, are patentable over Wallace et al. and Rowekamp, each taken alone or in combination. Favorable action is earnestly solicited and a finding of patentability of Claims 1, 2, 8, 9, 11, 12, 14-16, 22-24, 28, 31-34, 37, and 38 is respectfully requested.

Respectfully submitted,


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VIII. Claims Appendix

1. A tip cap for a syringe for a medicament, the syringe having a tip, said tip cap comprising a base portion having an upper surface and a lower surface, a body having a top wall extending from said upper surface and self-maintained in having a substantially non-circular cross-section in an unstressed condition when viewed at an angle substantially perpendicular to said upper surface, and a shaft extending from said lower surface, said shaft being shaped internally to releasably receive the tip of the syringe, wherein said tip cap defines a continuous and uninterrupted sealing surface which continuously seals the tip of the syringe and contains the medicament within the syringe when said tip is releasably received in said shaft of said tip cap and until said tip cap is removed from said syringe, the medicament within the syringe being accessible through the tip of the syringe with removal of said tip cap.

2. The tip cap of claim 1, wherein said non-circular cross-section is elliptical.

3. (Withdrawn) The tip cap of claim 1, wherein said non-circular cross-section is oval.

4. (Withdrawn) The tip cap of claim 1, wherein said non-circular cross section is rectangular.

5. (Withdrawn) The tip cap of claim 1, wherein said non-circular section is comprised of a pair of arcuate structures.

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6. (Withdrawn) The tip cap of claim 1, wherein said non-circular section is polygonal.

7. (Withdrawn) The tip cap of claim 1, wherein said non-circular section is comprised of a plurality of cylindrical structures arranged around the central axis of said tip cap.

8. The tip cap of claim 1, wherein said top wall includes a textured surface.

9. The tip cap of claim 8, wherein said textured surface includes a plurality of ribs.

10. (Withdrawn) The tip cap of claim 8, wherein said textured surface includes a plurality of dimples.

11. The tip cap of claim 1, wherein said top surface includes a plurality of ribs.

12. The tip cap of claim 1, further comprising means for connecting said tip cap to a syringe.

13. (Withdrawn) The tip cap of claim 12, wherein said means for connecting comprises a luer slip connection.

14. The tip cap of claim 12, wherein said means for connecting comprises a helical thread.

15. A syringe assembly comprising:

a syringe having a tip; and

a tip cap securable to said tip and comprising:

a base portion having an upper surface and a lower surface, a body having a top wall extending from said upper surface and self-maintained in having a substantially non-circular cross-section in an unstressed condition when viewed at an angle substantially perpendicular to upper surface, and a shaft extending from said lower surface, said shaft being shaped internally to releasably receive the tip of the syringe, wherein said tip cap defines a continuous and uninterrupted sealing surface which continuously seals the tip of the syringe and contains the medicament within the syringe when said tip is releasably received in said shaft of said tip cap and until said tip cap is removed from said syringe, the medicament within the syringe being accessible through the tip of the syringe with removal of said tip cap.

16. The syringe assembly of claim 15, wherein said non-circular cross-section is elliptical.

17. (Withdrawn) The syringe assembly of claim 15, wherein said non-circular cross-section is oval.

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18. (Withdrawn) The syringe assembly of claim 15, wherein said non-circular cross section is rectangular.

19. (Withdrawn) The tip cap of claim 15, wherein said non-circular section is comprised of a pair of arcuate structures.

20. (Withdrawn) The tip cap of claim 15, wherein said non-circular section is polygonal.

21. (Withdrawn) The tip cap of claim 15, wherein said non-circular section is comprised of a plurality of cylindrical structures arranged around the central axis of said tip cap.

22. The syringe assembly of claim 15, wherein said top wall is at least partially perimetrically disposed on said upper surface.

23. The syringe assembly of claim 15, wherein the exterior of said top wall further includes a textured surface.

24. The syringe assembly of claim 23, wherein said textured surface includes a plurality of ribs.

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25. (Withdrawn) The syringe assembly of claim 23, wherein said textured surface includes a plurality of dimples.

26. (Withdrawn) The syringe assembly of claim 23, wherein said textured surface includes a plurality of radially extended flanges.

27. (Withdrawn) The syringe assembly of claim 15, wherein said connection means is a luer slip connection.

28. The syringe assembly of claim 31, wherein said connection means is a helical thread.

29. (Withdrawn) The syringe assembly of claim 15, wherein a recessed well extends at least partially through said lower surface of said base portion.

30. (Withdrawn) The syringe assembly of claim 29, wherein, said syringe tip at least partially extends into said well with said tip cap covering said syringe tip of said syringe.

31. The syringe assembly of claim 15, wherein said tip cap further comprises connection means for attaching said tip cap to said tip.

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32. The tip cap of claim 1, wherein said top wall is at least partially perimetrically disposed on said upper surface.

33. The tip cap of claim 1, wherein the syringe is a medical syringe.

34. The syringe assembly of claim 15, wherein said syringe is a medical syringe.

35. - 36. (Cancelled).

37. The tip cap of claim 1, wherein said top wall is disposed along major and minor axes, said top wall having faces disposed along said major axis, said faces each having an arcuate profile along said major axis.

38. The syringe assembly of claim 15, wherein said top wall is disposed along major and minor axes, said top wall having faces disposed along said major axis, said faces each having an arcuate profile along said major axis.

IX. Evidence Appendix

Appellants do not have any evidence to include in the Evidence Appendix.

X. Related Proceedings Appendix

Appellants are not aware of any related proceedings.